

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/019,048

Applicant(s)

HEINZ ET AL.

Examiner

CATHERINE HIBBERT

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-3, 6, 8-10, 13 and 18-21.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: see attachment.

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636

Catherine S. Hibbert
Examiner/Au1636

Continuation of 11, does NOT place the application in condition for allowance because: All rejections stated in the last office action remain. No claims are allowed. The amendment to the claims will not be entered. The reasons are as follows:

1. In claim 1, item c, the "said polypeptide still having $\Delta 6$ desaturase activity" is broad but is nevertheless unclear as to which activity the polypeptide has or has retained. Is it the catalytic activity or the substrate binding activity or some other activity? See, e. g., $\Delta 6$ desaturase catalytic activity instead.
2. In claim 1, neither the newly added recitation nor the deleted recitation result per se in preparing the poly peptide. Neither recitation nor any process steps require expression of the genetic material (transcription and translation) as a protein. Please note that "culturing the organism" does not invariably and inevitably result in protein production of a desired protein.
3. In claim 9, the 95% identity (homology is evolutionary relatedness and not identity) creates an issue of which 5% of the sequence(s) can be changed such that activity (currently undefined in the claim(s)) is retained. The remarks in the response do not point to any parts of the specification as support for what parts of the sequence must be conserved and what parts can be altered (the protein SEQ ID NO: 1 is 525 amino acids and 5% of 525 is 26.25 residues at the amino acid level and 75 bases at the DNA level). Of note is that the specification and claims refer to "not substantially reduced" as having 10, 20 or 30% of the enzymatic activity, however it is not clear how these low percentages are not substantial since 10% retention of catalytic activity is 10 times lower and 30% is at least 3 times lower than the 100% mark (using the unmodified enzyme as fully functional and active). See specification page 10 and 11s. Given at least the above as assessment of the claims, issues under 35 U.S.C. 112 written description, enablement, and second paragraph would be raised independent of whether or not any art rejections are overcome.

The discussion of priority (response page 5, bottom paragraph) based on the '531 application is noted but unpersuasive even with citation of M. P. E. P. sections. There is neither a factual analysis of the prior application disclosure nor does the response point to any pages, paragraphs, etc. of the priority application that demonstratively show the written description and enablement. It is also noted that page 6 cites Capon as standing for five (5) factors to support generic claims. In this instance, and as pointed out above for the '531 application, there is no factual analysis presented in the current response of the prior application nor does the response point to any pages, paragraphs, etc. of the priority application that demonstratively show the written description and enablement. As to the issue of foreign priority document translations to be provided, no documents have been presented. Thus, the priority remains as stated in prior office actions...

Page 7 of the response discusses the rejection(s) under 35 U.S.C. 102(b) over Girke et al. and 102(a) over Napier et al. as overcome based on the '531 application and because the Girke et al. application is less than one year prior. As stated above the absence of demonstration and/or citation of specific passages in the '531 document, the reasoning presented in this section of the response is unpersuasive.

In the section discussing the 35 U.S.C. 112 rejection (response pages 6-7), the comments refer to cancellation of (1) 1 to 80 mol% and (2) claim 20-21. The comments are unpersuasive in view of the unentered status of the amendment.